ID NO:2; wherein the fragment can competitively inhibit the biological activity of IL-6 in a suitable assay system by binding to the IL-6 receptor.

REMARKS

Claims 13-17, 29-33 and 36-53 are pending and claims 36-53 were examined in the last office action mailed November 27, 2002. Claims 36-39, 43, 45, 47-49, 52 and 53 are allowed. Claims 40, 41 and 44 are objected to and claims 42, 46, 50 and 51 stand rejected. In response, unexamined claims have been cancelled, other claims have been amended and arguments are set forth regarding patentability of claims. The phrase " wherein the fragment can competitively inhibit the biological activity of IL-6 in a suitable assay system by binding to the IL-6 receptor" added to claim 51 is supported, for example, by the recitation of claim 42 and is not new matter.

Reconsideration and allowance of claims 40-42, 44, 46, 50 and 51 earnestly are solicited.

The Objections to Claims 40, 41, and 44

The Examiner objected to these claims because of the use of the indefinite article in their preambles. In response, the term "the" has been substituted for each claim.

Removal of the objection is solicited.

Rejection of Claims 42 and 50 under 35 U.S.C. § 112:

Claim 42 was rejected on alleged indefiniteness grounds. In response, applicants have replaced "the" with "a" and added the clarifying term " IL-6" in front of "the receptor" in line 3.

Reconsideration and allowance are requested.

Claim 50 was rejected on alleged indefiniteness grounds. In response, applicants have amended this claim to recite the subject matter of 46 (isolated nucleic acid).

Reconsideration and allowance are requested.

Rejection of Claims 46, 50 and 51 under 35 U.S.C. § 102(e):

Claims 46, 50 and 51 are rejected over a patent, U.S. No. 5,861,240 that describes the cloning of genomic DNA from BCBL-1 that has latent HHV-8 infections.

The Examiner opines at the middle of page 3 of the office action that "the composition and function as claimed are presumed inherent....."

In response, applicants have amended these claims to recite the products of recombination and point out that such recombinant product is not inherent in the cited art.

Recombinant v-IL-6 products are not in the cited art, either explicitly or inherently because the cited reference clearly indicates this as seen in a three part analysis. One, "the library of cloned fragments screened in FIG. 1 does not include the complete viral genome" as described by the text of this reference on column 11 lines 28-30. Two, "[t]he nucleotide sequences of the genomic loci corresponding to these RNAs was determined and compared with their respective cDNA sequences" (column 12, lines 25-27 of the cited patent). This paragraph summarizes in some detail the discovered information from these sequences, which do not cover the entire HHV-8 genome. The listed inventors of the cited art did not make an astonishing discovery of similarity between their new sequences and a known mammalian IL-6 gene. Three, if any of the nucleic acids prepared were homologous to a known gene, the cited authors would have noticed that homology. The homology analysis, is routine, is inherent in such work and is referred to in the reference itself. The authors obviously checked to see if their new sequences were homologous to known sequences and in fact report "[t]he sequence of the 5' orf has no homologs in the GenBank data base" in connection with another observation of a translated sequence "hydrophobic nature."

Because only part of the virus was cloned, the cloned part was sequenced, and the authors would have, reported trying, but failed to notice homology to known genes, the v-IL-6 gene was not cloned in the cited art and cannot be inherent. Applicants note that the Examiner further opines that "the cited art clearly teaches the identification of expressed viral genes in infected and uninfected cells...." on the top of page 3 of the office action. The amended claims now recite recombinant products, which are not present, either explicitly or inherently in such conditions, because non-viral synthesis literally differs from the cited description.

Because the amended claims recite a recombinant product that is not present in the cited art or conditions, even inherently, reconsideration and allowance earnestly are requested.

CONCLUSION:

In view of the foregoing, Applicants respectfully request the Examiner to withdraw the rejections against claims 42, 46, 50 and 51. The Examiner is invited to contact the undersigned attorney to resolve any issues, in order to expedite the prosecution of the application.

Respectfully submitted,

March 26, 2003

Marvin A. Motsenbocker
Reg. No. 36,614

HELLER EHRMAN WHITE & McAULIFFE
1666 K Street, NW, Suite 300
Washington, DC 20006-1228
(202) 912-2000 (telephone)

Marked-UP Copy of Claims

40. [A]The fragment as claimed in claim 39, which consists of the amino acid sequence (residues 87-105 of SEQ ID NO:2) GFNETSCLKKLADGFFEFE.

41. [A]The fragment as claimed in claim 39, which binds to a human IL-6 receptor.

42. A fragment obtained from the human viral interleukin-6 (v-IL-6) of claim 36 that binds to [the]an IL-6 receptor and which can competitively inhibit the biological activity of IL-6 in a suitable assay system wherein the fragment binds to the IL-6 receptor.

44. [An]The isolated nucleic acid as described in claim 43, consisting of the nucleotide sequence of SEQ ID NO: 1.

46. An isolated nucleic acid molecule prepared by recombinant expression, hybridizing under stringent conditions to the nucleic acid as claimed in claim 44, encoding functional v-IL-6, wherein the nucleic acid encodes functional v-IL-6.

50. A cell culture growth medium, comprising the [recombinantly produced v-IL-6 as claimed in] isolated nucleic acid molecule of claim 45, wherein the isolated nucleic acid molecule is produced by recombination.

51. A fragment of a polypeptide that is obtainable by recombinant expression of the DNA of HHV-8 in an isolated cell and which comprises the amino acid sequence of SEQ ID NO:2; wherein the fragment can competitively inhibit the biological activity of IL-6 in a suitable assay system by binding to the IL-6 receptor.